

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION**

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	Master File No. 2:12-MD-02327 MDL No. 2327
THIS DOCUMENT RELATES TO: <i>Wave 2 Cases</i>	JOSEPH R. GOODWIN U.S. DISTRICT JUDGE

**PLAINTIFFS' MEMORANDUM IN REPLY TO DEFENDANTS' OPPOSITION
TO PLAINTIFFS' MOTION TO EXCLUDE DR. LARRY T. SIRLS'
TVT/TVT-O GENERAL OPINIONS**

Now come Plaintiffs in reply to Defendant Ethicon, Inc.'s ("Ethicon") Opposition to Plaintiffs' Motion to Exclude Dr. Larry T. Sirls' ("Dr. Sirls") TVT/TVT-O General Opinions ("Ethicon's Opposition") filed with the Court December 13, 2016 (DKT 3271).¹ Plaintiffs stand on their Motion to Exclude the General Opinion Testimony of [Dr. Sirls] and the legal memorandum in support thereof, both filed with the Court on July 29, 2016 ("Plaintiffs' Motion") (DKT 2480)² and move that Dr. Sirls' testimony be excluded as set forth therein. In addition, Plaintiffs now say the following in reply to certain points raised in the Ethicon Opposition.³

I. ARGUMENT

**A. THAT DR. SIRLS QUALIFIES AS A UROGYNECOLOGIST DOES NOT
INDICATE THAT HE IS EQUALLY QUALIFIED TO PROFFER THE
OPINIONS CHALLENGED BY PLAINTIFFS' MOTION**

¹ Future citations to Ethicon's Opposition will be in the form (Eth. Opp. ____).

² Future citations to Plaintiffs' Motion will be in the form (Pl. Mot. ____).

³ Plaintiffs note for the record that failure to reply to any particular point in the Ethicon Opposition does not signal agreement with Ethicon but, rather, that the point is already addressed sufficiently in Plaintiffs' Motion and requires no further explication.

The Ethicon Opposition provides a lengthy description of Dr. Sirls' qualifications. (Eth. Opp. 3-5.) However, nothing in Dr. Sirls' background or credentials renders him qualified to proffer the opinions now challenged by Plaintiffs including 1) any and all regarding the biochemical or material aspects of polypropylene mesh, and 2) any and all he purports to proffer concerning the adequacy of the warnings in the instructions for use ("IFU") accompanying Ethicon's TVT and TVT-O devices. (Pl. Mot. 2, 4-6.) Ethicon concedes the merits of Plaintiffs' position to the first, at least in part, stating that "Dr. Sirls does not purport to opine on the details of the chemical composition and properties of [the materials comprising the TVT and the TVT-O]" and also that he "may not be qualified to offer advanced pathology opinions but [also that] he does not purport to offer such opinions." (*Id.*, 13-14.) Dr. Sirls' expert opinion testimony should be so limited at trial.

In addition, with regard to Dr. Sirls' opinions on the adequacy of Ethicon's warnings in its IFUs, such should be excluded not only because, as even Ethicon agrees, Dr. Sirls is admittedly unqualified to proffer opinions regarding the *legal* adequacy of warnings (*id.*, 11)(Ethicon stating that Dr. Sirls "will not be offered to opine on whether the IFU was legally 'adequate'") but need also be excluded to the extent they are grounded in matters beyond his clinical experience. Ethicon argues that Plaintiffs cite improperly to this Court's earlier opinion in *Sederholm v. Boston Scientific Corp.*, No. 2:13-cv-12510, 2016 WL 3282587 at *16 (S.D.W. Va. June 14, 2016). However, the Court's holding in *Sederholm* is applicable to Dr. Sirls' opinions here. As did the medical expert in *Sederholm*, Dr. Sirls purports to proffer that an IFU is adequate because it includes those complications that he has experienced with his patients in own clinical practice. (See Pl. Mot. 5 and cites therein.) However, the Court in *Sederholm* determined that simply because a company's warnings included the particular risks a doctor encountered in his practice

did not mean that the warnings were also sufficient to warn patients of *all* the risks attendant to the device in question. *See Sederholm*, 2016 WL 3282587 at *16 (the Court holding that there is a “clear distinction” between a case where an expert testifies that a DFU (IFU) is *inadequate* grounded in his clinical experience (which the Court found would be admissible) and where the expert offers opinion that it is *adequate* because it is in accord with his clinical experience (which would not be admissible)) (“Finding reason to exclude evidence where [i]n the present case, [Defendants’] experts have observed certain risks and complications in their practice which are warned of in the DFU, and therefore, deduce that there are no possible risks or complications that should have been included.”). In like manner, simply because Dr. Sirls found the IFU in question to be adequate because it covered the risks he encountered in his own practice does not mean that it was legally-adequate to warn patients of each and all of the risks that Ethicon was aware of regarding the TVT and the TVT-O and of which it had a duty to warn potential recipients of its devices. An example of one such opinion to be excluded was when Dr. Sirls testified:

As a pelvic surgeon, I know all of these things. So these things, this is adequate for me because my knowledge base augments and supersedes this information. *So I find this to be adequate.*

(*See* Dr. Sirls’ deposition testimony of July 21, 2016 at 78:10-13)(emphasis added)⁴

Still other examples are set forth in Plaintiff’s Motion. (*See* Pl. Mot. 5 and all citations therein.)(*See also* 79:12-80:20.) Dr. Sirls’ opinions that Ethicon’s IFUs were adequate should be excluded for the same reason the Court excluded the expert opinion in *Sederholm*, 2016 WL 3282587 at *16.

Additionally, contrary to the Ethicon Opposition, Dr. Sirls did not ground his opinions about the alleged adequacy of Ethicon’s IFUs in the available clinical literature. (Eth. Opp. 10)(arguing that Dr. Sirls relied on “several sources of different information,” and not just his

⁴ Relevant excerpts of Dr. Sirls’s deposition transcript is attached hereto as Exhibit A. Future references to Exhibit A will be in the form (Ex. A, ____:____; ____:____.).

clinical experience, seeking to distinguish his opinions from those excluded in *Sederholm*.). In fact, Dr. Sirs, when questioned why Ethicon chose to leave information out of the TVT and TVT-O IFUs regarding the devices' very unique and disparate risk profiles, Dr. Sirs testified that the two IFUs were nevertheless "adequate," even though the information supplied by Ethicon did not include what he, himself, found necessary to provide during "forty-five minute discussion(s)" with pre- implant TVT/TVT-O patients (*see* Ex. A, 80:8-10) and was also directly contrary to a study by Dr. Schimpf and colleagues that Dr. Sirs admitted during his deposition included "great documents and meta-analyses of the literature." (*Id.*, 81:3-4.) Dr. Sirs justified Ethicon's deliberate leaving of information about the different risk profiles of the TVT and TVT-O out of its IFUs, saying the information was "intuitive" to physicians, thereby somehow rendering the IFUs not inadequate by its absence from the company-provided warning literature. (*Id.*, 81:21-82:2; 82:20-22.) However, these are precisely the types of opinions that the Court in *Sederholm* excluded as unreliable, *see* 2016 WL 3282587 at *16, and Plaintiffs respectfully submit that the Court should do so here again.

B. AS ARGUED IN FULL IN THE PLAINTIFFS' MOTION, DR. SIRLS CANNOT PROPERLY GROUND HIS OPINIONS ABOUT ETHICON'S TVT OR TVT-O DEVICES IN HIS CLINICAL EXPERIENCE WITH THE TVT-ABBREVO

Plaintiffs largely stand on their argument in the Plaintiffs' Motion that Dr. Sirs' opinions must be excluded to the extent they are grounded in his clinical experience with an Ethicon product entirely different from the TVT/TVT-O: the TVT-Abbrevio. (Pl. Mot. 4, 6, and cites therein.) As set forth in Plaintiffs' Motion, an expert may not testify "outside the scope of [his] expert opinion." (*Id.*)(quoting *Huskey v. Ethicon*, C. A. No. 2:12-cv-05201, 2014 WL 3861778 at *5 (S.D.W. Va. August 6, 2014)). And it is a clear fact that Dr. Sirs' expert report is confined to his opinions about

the TVT and TVT-O devices. (See Expert Report of [Dr. Sirls] dated June 3, 2016.)⁵ The fact that Dr. Sirls grounds his opinions regarding two specific devices with his clinical experience with a third makes the opinions unreliable and, therefore, subject to exclusion under *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993.).

II. CONCLUSION

For reasons of the forgoing, and as set forth more fully in Plaintiffs' Motion, the expert opinions of Dr. Sirls, should be limited or excluded.

Respectfully submitted,

Date: December 20, 2016

By: /s/ Fidelma L. Fitzpatrick
Fidelma L. Fitzpatrick
Motley Rice LLC
55 Cedar St., Suite 100
Providence, RI 02903
Phone: (401) 457-7700
Fax: (401) 457-7708
ffitzpatrick@motleyrice.com

Fred Thompson, III
Motley Rice LLC
28 Bridgeside Blvd.
Mount Pleasant, SC 29464
Phone: (843) 216-9000
Fax: (843) 216-9450
fthompson@motleyrice.com

Co-Lead Counsel MDL 2325

⁵ Dr. Sirls's expert report is attached hereto as Exhibit B.

CERTIFICATE OF SERVICE

I hereby certify that on December 20, 2016, I electronically filed the foregoing document with the Clerk of the court using CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

/s/Fidelma L. Fitzpatrick
Fidelma L. Fitzpatrick
Motley Rice LLC
55 Cedar St., Suite 100
Providence, RI 02903
Phone: (401) 457-7700
Fax: (401) 457-7708
ffitzpatrick@motleyrice.com

Fred Thompson, III
Motley Rice LLC
28 Bridgeside Blvd.
Mount Pleasant, SC 29464
Phone: (843) 216-9000
Fax: (843) 216-9450
fthompson@motleyrice.com

Co-Lead Counsel MDL 2325